

*M*  
*Hemophilus influenzae* immunogen, a BCG immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, polio, Hepatitis B, and pertussis.

*G3C2*  
*cont*  
*Gef*  
32 (twice amended). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, and, if said one immunogen is whole cell pertussis, the schedule is one other than a schedule of three doses at one week intervals, all given in the first month,

where, when all of the immunogens administered are selected from the group consisting of a BCG immunogen, *Hemophilus influenzae* immunogen and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, whole cell pertussis, polio, hepatitis B, measles, mumps and rubella, at least one of the following conditions applies: (a) one or more immunogens are administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less.

*G5*  
38 (amended). The kit of claim 59, wherein, according to said instructions, for at least one such immunogen which elicits an immune response to one of said infectious diseases, the total dosage during the first 112 days after birth is greater than that required for immunization against the infectious disease with which it is associated.

*G6*  
40 (amended). The kit of claim 27 wherein according to said instructions at least one immunogen is given in two or more dosings such that the shortest interval between two successive dosings thereof is at least one and less than 28 days.

*H1*  
56 (amended). A method of reducing the incidence or severity of an immune disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

*Ab*  
the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

*V3*  
where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, where, when all of the immunogens administered are selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, pertussis, polio, hepatitis B, measles, mumps and rubella, at least one of the following conditions applies: (a) one or more immunogens are administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum

*ff1*  
*cont*  
*W/C*  
*3*

interval between administrations is about two weeks, or less, and where one or more immunogens are administered on at least four different dates.

*PS*  
*PS*  
*PS*  
*PS*  
*PS*  
*PS*

67 (amended). The kit of claim 66 where said pediatric immunogen is selected from the group consisting of a BCG, immunogen, a *Hemophilus influenzae* immunogen, and an immunogen which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, [*hemophilus influenza*,] tetanus, hepatitis B, and polio.

*ff2*  
*ff3*  
*ff4*  
*ff5*  
*ff6*  
*ff7*

71 (amended). The kit of claim 43 in which at least one immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, BCG, *hemophilus influenza* and smallpox.

*G10*  
*G11*  
*G12*

73 (amended). The kit of claim 72 where said pediatric immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, hepatitis B, and polio.

77 (amended). The kit of claim 16 wherein at least one immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, and smallpox.

129 (amended). A method of protecting against an infectious disease which comprises providing a vaccine kit according to claim 59 comprising one or more immunogens protective against said disease, and instructions setting forth at least one immunization schedule for administering said immunogens, which, if followed, results in protection against such disease, said

instructions stating that one or more immunogens can be administered according to more than one immunization schedule

*(612)*  
and warning that administration according to different immunization schedules may have different effects on the incidence of a chronic immune mediated disorder;

so that adhering to said warnings in said instructions may lead to a lower incidence of said chronic immune mediated disorder.

*(613)*  
Please add the following new claims:

144 (new). A method of reducing the incidence or severity of a ~~chronic~~ immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

*(613)*  
the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

*(612)*  
wherein at least one immunogen is provided which is not any of the following immunogens: a BCG, a *Hemophilus influenzae*, *Streptococcus pneumoniae* or *Neisseria* immunogen, or an immunogen of an organism which causes diphtheria, tetanus, pertussis, polio, hepatitis A, hepatitis B, measles, mumps, rubella, influenza, cholera, plague, varicella, rabies, typhoid or yellow fever.

145 (new). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of

said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein at least one immunogen is administered on at least four different dates prior to 42 days after birth.

146 (new). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein for at least one such immunogen, the total dosage during the first 112 days after birth is greater than that required for immunization against the infectious disease with which it is associated.

147 (new). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in

the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein at least one immunogen so administered is one other than pertussis, and a plurality of doses of that immunogen are administered.

148 (new). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered before the mammal's immune system arrives at a state of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat,

where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, and, if said one immunogen is whole cell pertussis, the schedule is one other than a schedule of three doses at one week intervals, all given in the first month,

where, when all of the immunogens administered are selected from the group consisting of BCG, diphtheria, tetanus, whole cell pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, at least one of the following conditions applies: (a) one or more immunogens are administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum interval between administrations

*Sub. M*  
is about two weeks, or less.

149 (new). The kit of claim 68 in which said nonpediatric immunogen is selected from the group consisting of

(a) an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, encephalitis, meningitis, typhus, typhoid fever, Lyme disease, cholera, leprosy, varicella, dengue, influenza, herpes, rabies, toxoplasmosis, coccidiomycosis, schistosomiasis and malaria, and

(b) an immunogen selected from the group consisting of *Streptococcus*, *Staphylococcus*, *Neisseria*, *Escherichia coli*, *Shigella*, *Leishmania*, cytomegalovirus (CMV), respiratory syncytial virus, Epstein-Barr virus, herpes virus, parainfluenza virus, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A virus, NonA NonB hepatitis virus, and flavivirus immunogens.

*Ans*  
*TS*  
*GAB*  
150 (new). The kit of claim 74 in which said nonpediatric immunogen is selected from the group consisting of

(a) an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, encephalitis, meningitis, typhus, typhoid fever, Lyme disease, cholera, leprosy, varicella, dengue, influenza, herpes, rabies, toxoplasmosis, coccidiomycosis, schistosomiasis and malaria, and

(b) an immunogen selected from the group consisting of *Streptococcus*, *Staphylococcus*, *Neisseria*, *Escherichia coli*, *Shigella*, *Leishmania*, cytomegalovirus (CMV), respiratory syncytial virus, Epstein-Barr virus, herpes virus, parainfluenza virus, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A virus, NonA NonB hepatitis virus, and flavivirus immunogens.

151 (new). The kit of claim 43 in which at least one immunogen is selected from the group consisting of

(a) an immunogen of an organism which causes a disease selected from the group consisting of measles, mumps, rubella,